EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOKIA CORPORATION and NOKIA, INC.,	§	
	§	
Plaintiffs,	§	
v.	§	
	§	**Civil Action No. 05-16-JJF**
INTERDIGITAL COMMUNICATIONS CORPORATION and INTERDIGITAL TECHNOLOGY CORPORATION,	§	
	§	
Defendants.	§	

DECLARATION OF WILLIAM J. MERRITT

In accordance with 28 U.S.C. § 1746, I, William J. Merritt, declare as follows:

1. My name is William J. Merritt. I am over eighteen years of age, have never been convicted of a felony or crime of moral turpitude, and am fully competent to make this declaration.

2. I joined InterDigital Communications Corporation ("IDCC") in January 1996. From August 2001 until the present, I have served as General Patent Counsel of IDCC and President of InterDigital Technology Corporation ("ITC"). Prior to that period, I served in various executive positions at IDCC and ITC. In this declaration, I refer to IDCC and ITC collectively as "InterDigital."

3. I am authorized to provide this declaration on behalf of InterDigital. I am able to state the following facts based upon personal knowledge and the business records of InterDigital, and those facts are in all things true and correct.

4. InterDigital has a workforce of approximately 325 employees. The substantial majority of that workforce is its engineers, many of whom hold advanced engineering degrees. InterDigital has four research and development facilities which are located in King of Prussia, Pennsylvania (where the company also is headquartered); Melville, New York; Montreal, Canada; and Melbourne, Florida. With the exception of Montreal, each of its development centers has extensive laboratory facilities.

5. InterDigital was formed in 1992 by the merger of two predecessors that, throughout the 1980's, developed, improved, and patented digital wireless systems that provided for the efficient use of the

radio spectrum. One predecessor developed and patented a digital wireless system that utilized Frequency Division Multiple Access ("FDMA"), Time Division Multiplexing ("TDM"), and Time Division Multiple Access ("TDMA") (collectively, an "FD/TDMA System"), while the other predecessor developed and patented a digital wireless system that utilized spread spectrum Code Division Multiple Access ("CDMA").

6. In the late 1980's and early 1990's, the cellular industry (manufacturers and cellular service providers) cooperated in the development of second generation ("2G") digital wireless system standards – the GSM and US-TDMA FD/TDMA systems and the IS-95 CDMA system – which are widely deployed today. The US-TDMA and IS-95 standards were developed in the United States, while the GSM standard was developed in Europe.

7. Recognizing InterDigital's predecessors' unique knowledge and experience, the United States standards-setting bodies invited InterDigital's predecessors' participation in the development of the US-TDMA standards and adopted in these 2G standards many of their contributions and much of their patented intellectual property. Similarly, European standards-setting bodies incorporated in the GSM standard much of InterDigital's patented intellectual property.

8. Because of the pioneering work of its predecessors and the inclusion of its patented intellectual property in the 2G standards, InterDigital has entered into over thirty-five patent license agreements with the cellular industry.

9. "Standards" are approved instructions and guidelines for designing equipment. In the mobile telephone business, standards are adopted by national and international standards-setting bodies and ensure that equipment built by different vendors to the same standard will interoperate.

10. From their inception, InterDigital and its predecessors have focused on the patenting of their inventions. Today, ITC – IDCC's principal patent holding company – owns some 1,609 active issued patents and has over 5,077 active applications pending worldwide. Of this portfolio of active patents, over 480 issued patents originate from FD/TDMA-based development programs and 1,129 issued patents originate from CDMA-based development programs.

11. InterDigital's proven ability to conceive of new digital wireless access schemes and to transform these concepts into products has enabled it to become a technology company that designs and delivers advanced digital wireless solutions. InterDigital has

successfully used this ability under long-term agreements to develop third generation ("3G") digital wireless technology, which includes WCDMA and cdma2000 technology. Under these 3G agreements, InterDigital develops technology for a third party, owns intellectual property related to that technology, licenses that technology to the third party, and promotes the use of that technology in 3G applications. One such agreement was for the development of a complete Time Division Duplex technology platform for Nokia – the plaintiffs in this lawsuit. InterDigital also is the exclusive provider of certain WCDMA software to Infineon AG; it is the designated supplier of a complete WCDMA solution for the United States military's MUOS project; and it is the supplier to Amtel, Inc. of a smart antenna solution for wireless LAN products.

12. In January 1999, InterDigital and Nokia Corporation entered into a negotiated patent license agreement. Under that agreement, InterDigital granted to Nokia Corporation a worldwide non-exclusive license under essentially all of InterDigital's 1,609 active issued patents and 5,077 active pending patent applications. Those patents include InterDigital's TDMA and CDMA patents, which apply to 2G products such as GSM and US-TDMA, as well as 3G products such as WCDMA and cdma2000 products.

13. The amount of consideration paid and to be paid by Nokia Corporation under the patent license agreement is divided into two different periods. Period 1 ran through December 2001 and required Nokia Corporation to make an irrevocable and non-refundable payment of $31.5 million, which Nokia Corporation has paid. Period 2 runs from January 2002 to December 2006, and requires Nokia Corporation to pay royalties at market-defined rates upon the occurrence of InterDigital licensing a contractually-defined "Major Competitor" at royalties paid by this competitor, retroactive to the beginning of Period 2. Under this process, Nokia Corporation is treated as a most favored licensee of InterDigital and its royalty obligations during Period 2 are determined by reference to patent license agreements with defined Major Competitors, their successors and assigns, and purchasers of the assets that are the subject of the PLA.

14. One of the defined Major Competitors was Ericsson, Inc. and its successors or assigns, including purchasers of the assets that are the subject of the PLA. At the time InterDigital and Nokia Corporation entered into the patent license agreement in January 1999, InterDigital was engaged in patent litigation with Ericsson. In March 2003, InterDigital and Ericsson and Sony Ericsson (the purchaser of Ericsson's handset business) entered into patent

license agreements for 2G products at market-based running royalty rates. Those licenses triggered Nokia's Period 2 royalty obligations on Nokia's 2G products, which – given Nokia's market share – are very substantial.

15. Following the triggering of Nokia's Period 2 royalty obligations, Nokia Corporation and/or Nokia, Inc. have initiated the following adversarial proceedings against IDCC and/or ITC:

- On July 18, 2003, Nokia initiated an International Chamber of Commerce arbitration to vitiate any Period 2 royalty obligations on its 2G products (Case No. 12 829/JNWEBS; *Nokia Corporation, Claimant v. InterDigital Communications Corporation and InterDigital Technology Corporation, Respondents*; In the International Court of Arbitration of the International Chamber of Commerce).

  Nokia initiated that arbitration after it refused to comply with its Period 2 royalty obligations on Nokia's 2G products under the patent license agreement with InterDigital. The arbitration was conducted in January 2005, and the parties are awaiting the panel's decision;

- On June 14, 2004, Nokia filed a revocation proceeding in the United Kingdom seeking to revoke certain of InterDigital's U.K. patents as invalid as well as a declaration that these patents are not essential to the GSM standard (HC 04 CO1952; *Nokia Corporation v. InterDigital Technology Corporation*; In the High Court of Justice, Chancery Division Patents Court);

- On December 29, 2003, Nokia Corporation sought leave to intervene after the settlement of and entry of judgment in the prior litigation between InterDigital and Ericsson in order to seek reinstatement of certain orders vacated by the district court in that case (No. 3:93-CV-1809-M Consolidated with No. 3:93-CV-2119-M; *Ericsson Inc. v. InterDigital Communications Corporation and InterDigital Technology Corporation*; In the United States District Court for the Northern District of Texas).

  On June 8, 2004, the district court entered an order granting Nokia Corporation leave to intervene and granting Nokia Corporation's motion to reinstate certain orders previously vacated by the district court. InterDigital has appealed that order to the United States Court of Appeals for the Federal Circuit (No. 04-1484; *Ericsson Inc. v. InterDigital*

Communications Corporation and InterDigital Technology Corporation v. Nokia Corporation; In the United States Court of Appeals for the Federal Circuit). The parties presented oral argument on March 7, 2005 and are awaiting the panel's decision;

- On September 27, 2004 and September 28, 2004, Nokia Corporation filed two discovery actions pursuant to 28 U.S.C. § 1782 (No. 5:04-MC-29; *In re Application of Nokia Corporation for an Order of Discovery Pursuant to 28 U.S.C. § 1782*; In the United States District Court for the Eastern District of North Carolina / No. 4:04-MC-27; *In re Application of Nokia Corporation for an Order of Discovery Pursuant to 28 U.S.C. § 1782*; In the United States District Court for the Eastern District of Texas). Those actions were filed against Ericsson and Sony Ericsson but required responses by InterDigital due to indications that Nokia Corporation intended to use such discovery not merely in the U.K. revocation proceeding, as it claimed, but in the I.C.C. arbitration as well; and

- This lawsuit.

16. InterDigital has not yet entered into an agreement with a Major Competitor that would define and trigger payment of Nokia's Period 2 royalty obligation on Nokia's 3G products. Thus, Nokia's Period 2 royalty obligation continues to accrue at a yet to be defined royalty rate.

17. In their nearly thirty-year history, InterDigital and its predecessors have been involved in only five patent infringement lawsuits in defense of their intellectual property rights, and three of those lawsuits were commenced by the infringing party. Since January 1995, InterDigital has filed only one patent infringement action in defense of its intellectual property rights. None of the above lawsuits has involved Nokia or any of the patents currently in dispute in this case.

18. Nokia and InterDigital negotiated their current patent license agreement on and off for over a decade, without either party ever filing suit against the other party.

19. The patent license agreement between InterDigital and Nokia Corporation is set to terminate by its terms on December 31, 2006. InterDigital has offered to extend a license to Nokia Corporation beyond December 31, 2006. InterDigital remains receptive to entering such a license. Additionally,

InterDigital has committed to license its essential 3G patents for the WCDMA and cdma2000 standards on fair, reasonable, and nondiscriminatory terms.

20. This lawsuit was filed by Nokia on January 12, 2005 – just five days before the hearing in the I.C.C. arbitration between Nokia Corporation and InterDigital started on January 17, 2005 – and without any advance warning or notice by Nokia.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 15, 2005.

William J. Merritt

EXHIBIT 2

LEXSEE 2005 U.S. APP. LEXIS 1078

TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant, v. PFIZER INC., Defendant-Appellee.

04-1186

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

395 F.3d 1324; 2005 U.S. App. LEXIS 1078

January 21, 2005, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the District of Massachusetts. Judge Richard G. Stearns United States Court of Appeals for the Federal Circuit. *Teva Pharms. USA, Inc. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 21940 (D. Mass., Dec. 8, 2003)*

DISPOSITION: Affirmed.

LexisNexis(R) Headnotes

COUNSEL: Henry C. Dinger, Goodwin Procter LLP, of Boston, Massachusetts, argued for plaintiff-appellant. Of counsel on the brief was Thomas J. Meloro, Jr., Kenyon & Kenyon, of New York, New York.

Dimitrios T. Drivas, White & Case LLP, of New York, New York, argued for defendant-appellee. With him on the brief were Jeffrey J. Oelke and Adam Gahtan.

William A. Rakoczy, Rakoczy Molino Mazzochi LLP, of Chicago, Illinois, for amicus curiae Generic Pharmaceutical Association. With him on the brief was Lara E. Monroe-Sampson.

Sarah Lenz Lock, AARP Foundation Litigation, of Washington, DC, for amicus curiae AARP. With her on the brief was Bruce Vignery. Of counsel on the brief was Michael Schuster, AARP, of Washington, DC.

William L. Mentlik, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, of Westfield, New Jersey, for amicus curiae IVAX Pharmaceuticals, Inc. With him on the brief was Roy H. Wepner.

Lawrence DeMille-Wagman, Attorney, Federal Trade Commission, of Washington, DC, for amicus curiae Federal Trade [**2] Commission. With him on the brief were William E. Kovacic, General Counsel; Susan A. Creighton, Director, Bureau of Competition; John F. Daly, Deputy General Counsel for Litigation; and Lore A. Unt, Counsel for Intellectual Property.

JUDGES: Before * MAYER,CLEVENGER, and SCHALL, Circuit Judges. Opinion for the court filed by Circuit Judge SCHALL. Dissenting opinion filed by Circuit Judge MAYER.

* Judge Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

OPINIONBY: SCHALL

OPINION: **[*1326]** SCHALL, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") is a manufacturer of generic pharmaceuticals. In July of 2002, it filed an Abbreviated New Drug Application ("ANDA") pursuant to the provisions of the *Hatch-Waxman Amendments* to the *Federal Food, Drug and Cosmetic Act*. In its ANDA, Teva sought the approval of the Food and Drug Administration ("FDA") to market its generic version of the drug sertraline hydrochloride. Sertraline hydrochloride is sold under the trade name Zoloft tm by Pfizer, Inc. ("Pfizer"). Pfizer holds two patents relating to Zoloft tm: *U.S. Patent No. 4,356,518* (the "'518 patent") and *U.S. Patent No. 5,248,699* (the "'699 patent").

When Teva filed its **[**3]** ANDA, it also filed what is called in Hatch-Waxman parlance a "paragraph III certification." In that certification, Teva stated that it would not market its generic drug until the '518 patent expires. Simultaneously, Teva filed a **[*1327]** Hatch-Waxman "paragraph IV certification." In that certification, Teva stated that its generic drug did not infringe the '699 patent or, alternatively, that the '699 patent is invalid. The '699 patent expires after the '518 patent. Pursuant to the provisions of the Hatch-Waxman Amendments, Pfizer had forty-five days from the date it received notice of Teva's paragraph IV certification to sue Teva for infringement of the '699 patent, and during that period the statute barred Teva from filing a declaratory judgment action against Pfizer based upon its ANDA.

On January 24, 2003, after Pfizer failed to sue Teva within the forty-five-day period following Pfizer's receipt of notice of the paragraph IV certification, Teva filed a declaratory judgment action against Pfizer in the United States District Court for the District of Massachusetts. In its suit, Teva sought a determination that its generic drug did not infringe Pfizer's '699 patent or that the claims **[**4]** of the '699 patent were invalid. On December 8, 2003, the district court dismissed Teva's suit for lack of jurisdiction. It did so on the ground that Teva had failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, *28 U.S.C. § 2201(a)*. n1 *Teva Pharms. USA, Inc. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 21940, No. 03-CV-10167-RGS (D. Mass. Dec. 8, 2003)*.

n1 Unless otherwise indicated, all statutory references are to the 2003 version of the United States Code.

Teva now appeals the decision of the district court, claiming that the court erred as a matter of law in holding that there was no actual controversy between it and Pfizer. The court determined that Teva failed to show that Pfizer had taken actions giving rise to a reasonable apprehension on its part that Pfizer would sue it for infringement of the '699 patent. Having considered the arguments of the parties and several amici, n2 we see no error in the district court's ruling that Teva failed **[**5]** to establish that an actual controversy existed between it and Pfizer. We therefore affirm.

n2 Amicus Curiae Ivax Pharmaceuticals, Inc. submitted a brief in support of Pfizer urging affirmance. Amici Curiae the Federal Trade Commission, the Generic Pharmaceutical Association, and AARP submitted briefs in support of Teva urging reversal.

BACKGROUND

I.

A. The Hatch-Waxman Amendments

The Hatch-Waxman Amendments were e nacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at *21 U.S.C. § § 355*, *360cc*, and *35 U.S.C. § § 156*, *271*, *282*). In the Amendments, Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. *Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002)*.

In order to speed up the **[**6]** approval process for generic drugs, the Amendments provide that a generic drug manufacturer may submit an ANDA for approval by the FDA, rather than a full New Drug Application ("NDA"). The ANDA may rely on the safety and efficacy studies previously submitted as part of the NDA by demonstrating the generic drug's bioequivalence with the previously approved drug product. See *21 U.S.C. § 355(j)(2)(A)*. Under *35 U.S.C. § 271(e)(1)*, it is not an act of patent infringement to engage in otherwise **[*1328]** infringing acts necessary to prepare an ANDA. However, *section 271(e)(2)*(provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. *35 U.S.C. § 271(e)(2)*.

The Hatch-Waxman Amendments provide that NDA-holders must notify the FDA of all patents that "claim[]the drug for which the [NDA] applicant submitted the application ... and with respect to which a claim of patent infringement could reasonably be asserted ...." *21 U.S.C. § 355(b)(1)*, *(c)(2)*. The FD A lists such patents in the publication "Approved **[**7]** Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). As part of the approval process, an ANDA applicant must make one of four certifications with respect to each patent listed in the Orange Book that claims the drug for which it is seeking approval: (I) no such patent information has been submitted to the FDA; (II) the patent has expir ed; (III) the patent is set to expire on a certain date; or (IV) the patent is in valid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. *21 U.S.C. § 355(j)(2)(A)(vii)(I-IV)*. These are commonly referred to as paragraph I, II, III, and IV certifications.

Upon filing a paragraph IV certification as part of an ANDA, an applicant must give notice to the patentee and the NDA holder. The notice must include a detailed statement of the factual and legal bases for the opinion of the applicant that the patent is invalid or will not be infringed. *21 U.S.C. § 355(j)(2)(B)(i)*. If the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic **[**8]** thirty-month "stay" goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires. *21 U.S.C. § 355(j)(5)(B)(iii)*. During this forty-five day period, the ANDA applicant is barred from filing a declaratory judgment action with respect to the patent at issue. Id. If no infringement action is filed during this forty-five day period, the FDA may approve the ANDA. Id.

The first ANDA applicant to file a paragraph IV certification enjoys a 180-day period of generic marketing exclusivity, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product. *21 U.S.C. § 355(j)(5)(B)(iv)*. This provision provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to "design around" patents to find alternative, non-infringing forms of patented drugs. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study 57 (July 2002). The 180-day exclusivity period typically begins on the date of the first commercial marketing of the drug by the first applicant. *21 U.S.C. § 355 (j)(5)(B)(iv)*. **[**9]** The original Hatch-Waxman Amendments provided that the commencement of the 180-day exclusivity period could also be triggered by "the date of a decision of a court ... holding the patent which is the subject of the certification to be invalid or not infringed." n3 Id.

n3 As discussed in Part I. B., infra, in 2003 Congress enacted a more complex set of provisions relating to the 180-day exclusivity period. However, these new provisions do not apply in this case.

B. The 2003 Medicare Amendments

Congress recently enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. The Act was signed into law on December 8, 2003. Title **[*1329]** XI of the Act, entitled "Access to Affordable Pharmaceuticals," makes numerous changes in the Hatch-Waxman Amendments ("Medicare Amendments"). Among the changes is a provision for a "civil action to obtain patent certainty." *21 U.S.C. § 355(j)(5)(C)* (Supp. 2004). Pursuant to that **[**10]** provision, if the patentee or NDA-holder does not bring an infringement action within forty-five days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the applicant seeks approval. Id. In exchange, the ANDA applicant must make an offer of confidential access to its ANDA application so that the patentee or the NDA-holder can evaluate possible infringement. Id. The Medicare Amendments also provide that when the above circumstances are met, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under *section 2201* of title 28 for a declaratory judgment that such patent is invalid or not infringed." *35 U.S.C. § 271(e)(5)*((Supp. 2004).

Congress also addressed the statutory scheme surrounding the 180-day market exclusivity period. Congress replaced the traditional court decision "trigger" with a more complex set of 180-day provisions. See *21 U.S.C. § 355(j)(5)(D)* (Supp. 2004). However, **[**11]** the Medicare Amendments provide that these new forfeiture provisions are effective only with respect to those applications filed after December 8, 2003, for which no paragraph IV certification was made before December 8, 2003. Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b), 117 Stat. at 2460. Thus, the new forfeiture provisions do not apply in this case.

II.

A. The *'518* and '699 Patents

Pfizer's '518 patent, which expires on June 30, 2006, is directed to the chemical compound sertraline hydrochloride, which is useful for the treatment of mental depression

and anxiety disorders. n4 Sertraline hydrochloride operates by interacting with serotonin, a chemical messenger that participates in the transmission of nerve impulses in the brain. Sertraline hydrochloride works to selectively block the uptake of serotonin by synaptic cells, thus reducing its re-entry into nerve cells and allowing serotonin levels between nerve cells in the brain to build up. Pfizer's '699 patent, which expires on September 28, 2010, is direct ed to a novel crystalline form of sertraline hydrochloride and to a method for preparing it. n5 The commercial embodiment of **[**12]** the *'518* and '699 patents is the drug Zoloft tm, a hugely successful drug which has been approved by the FDA for treatment of mood and anxiety disorders. According to Pfizer's Annual Report, Zoloft tm generated revenues for the company in excess of $ 2 billion in 2002.

n4 The '518 patent was due to expire on December 30, 2005. However, the district court opinion explains that the FDA granted Pfizer a six-month pediatric exclusivity extension for the drug, pursuant to *21 U.S.C. § 355a*, making June 30, 2006 the effective expiration date of the patent.

n5 The district court's opinion recites that the '699 patent expires on September 29, 2010. We note that the electronic version of the Orange Book located on the FDA's website indicates that the '699 patent also was granted a six-month pediatric exclusivity extension.

B. Ivax Pharmaceuticals USA, Inc.'s ANDA filing relating to generic sertraline hydrochloride tablets

Ivax Pharmaceuticals USA, Inc. ("Ivax") is a manufacturer **[**13]** of generic pharmaceuticals. **[*1330]** In 1999, Ivax, then known as Zenith Goldline Pharmaceuticals, Inc., submitted an ANDA to the FDA for its generic version of sertraline hydrochloride. Since Pfizer had listed both the *'518* and '699 patents in the Orange Book in connection with its NDA for Zoloft tm tablets, Ivax was required to file a certification with respect to each patent as part of its ANDA. Ivax filed a paragraph III certification as to the '518 patent, stating that it was not seeking to market its generic version of sertraline hydrochloride prior to the expiration of the patent. Simultaneously, Ivax filed a paragraph IV certification as to the '699 patent, stating that its generic drug did not infringe the '699 patent, or alternatively, that the '699 patent was invalid.

Within forty-five days of its receipt of notice of Ivax's paragraph IV certification, Pfizer filed suit against Ivax for infringement of the '699 patent in the United States District Court for the District of New Jersey. Pfizer, Inc. v. Ivax Pharms. Inc., Nos. 00-408, 01-6007 (D. N.J. Jan. 1, 2000). In 2002, Pfizer and Ivax entered into a settlement agreement whereby Pfizer agreed to grant Ivax a royalty-bearing **[**14]** license on the '699 patent until its expiration in 2010. As a consequence of the agreement, Ivax is in a position to begin marketing its generic version of Zoloft tm immediately upon expiration of the '518 patent on June 30, 2006.

As the first-filer of an ANDA for the generic version of Zoloft tm, Ivax is entitled, under *21 U.S.C. § 355(j)(5)(B)(iv)*, to a 180-day generic market exclusivity period. This 180-day period will be triggered by the earlier of: (1) the first date of commercial marketing by the first generic applicant or (2) a "decision of a court ... holding the patent which is the subject of the [paragraph IV certification] to be invalid or not infringed." *21 U.S.C. § 355(j)(5)(B)(iv)(I-II)*.

C. Teva's ANDA filing relating to generic sertraline hydrochloride tablets

As noted, in July of 2002, Teva subm itted an ANDA to the FDA for its generic version of Zoloft tm. Like Ivax, Teva filed a paragraph III certification as to the '518 patent and a paragraph IV certification as to the '699 patent. Pfizer elected not to file suit against Teva for infringement of the '699 patent within the forty-five days following receipt **[**15]** of notice of Teva's paragraph IV certification, and to date no such suit has been filed.

D. Teva's declaratory judgment action

On January 24, 2003, Teva filed a declaratory judgment action in the United States District Court for the District of Massachusetts, seeking a declaration that its generic version of Zoloft tm does not infringe the '699 patent and a declaration that the '699 patent is invalid. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of the absence of an actual controversy, as required by Article III of the Constitution. On December 8, 2003, the court granted Pfizer's motion to dismiss.

In addressing Pfizer's motion, the district court applied the two-part test formulated by this court to determine whether an actual controversy exists in a patent infringement suit. Under that test, there must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, **[**16]** or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity. See *Amana Refrigeration, Inc v. Quadlux, Inc. ,172 F.3d 852, 855 (Fed. Cir. 1999)*. The district court determined **[*1331]** that Teva had satisfied the second prong of the test by filing its ANDA for generic sertraline hydrochloride. However, the court concluded that Teva had failed to satisfy the "reasonable apprehension" prong of the test.

Before the district court, Teva argued that Pfizer had created a reasonable apprehension of suit based upon the following considerations: (1) Pfizer had listed the '699 patent in the Orange Book; (2)Pfizer had refused to grant Teva a covenant not to sue; (3) Pfizer had aggressively asserted its patent rights against alleged infringers of other patents; (4) Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride; and (5) it was in Pfizer's self-interest to leave a "cloud of litigation" hanging over Teva. With respect to the final consideration, Teva argued that Pfizer's settlement with Ivax gave Pfizer a vested in terest in seeing Ivax preserve its 180-day exclusivity period.

The district court rejected Teva's contentions. **[**17]** First, the court noted that a blanket inference that, by listing a patent in the Orange Book, a patentee has declared its intention to sue any potential infringer would virtually eliminate the "reasonable apprehension" prong of the two-part test. Second, the court stated that there is nothing in the Federal Food, Drug, and Cosmetic Act that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Third, the court found that Teva's subjective belief that it would be sued because Pfizer sued Ivax does not amount to an explicit threat indicating the imminence of suit. Finally, the court reasoned that, if anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospect of an immediate lawsuit against Teva even less likely.

Teva timely appealed the district court's decision. We have jurisdiction pursuant to *28 U.S.C. § 1295(a)(1) (2000)*.

ANALYSIS

I.

Our starting point is the Declaratory Judgment Act, *28 U.S.C. § 2201(a)*, the statute under which Teva filed its suit. The Act provides in relevant part as follows:

> In a case of actual controversy within its **[**18]** jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

The Act, which parallels Article III of the Constitution, "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996)*. Generally, the presence of an "actual controversy," within the meaning of the Act, depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id. (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273, 85 L. Ed. 826, 61 S. Ct. 510 (1941)*). Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has substantial discretion to decline that jurisdiction. Id.; see also *Wilton v. Seven Falls Co., 515 U.S. 277, 286, 132 L. Ed. 2d 214, 115 S. Ct. 2137 (1995)* **[**19]** (reaffirming that since its inception, "the Declaratory Judgment Act has been understood to confer on federal **[*1332]** courts unique and substantial discretion in deciding whether to declare the rights of litigants"). As we summarized in *Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631, 634 (Fed. Cir. 1991)*: "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary." n6

> n6 Because the district court dismissed Teva's suit for lack of jurisdiction, it did not reach the stage of exercising its jurisdiction to determine whether to entertain the suit.

As noted, this court has developed a two-part inquiry to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity. *EMC Corp., 89 F.3d at 811*. The inquiry focuses on the conduct of both the patentee and the potential infringer. *Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376, 1380 (Fed. Cir. 2004)*. **[**20]** There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *Id.*; *Amana Refrigeration, 172 F.3d at 855*; *BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993)*.

Teva contends on appeal that the district court erred in ruling that it had failed to demonstrate the existence of an actual controversy between it and Pfizer under our two-part test. Teva argues that it had reasonable, objective grounds to fear that Pfizer would bring an action for infringement of the '699 patent. Teva also argues that the

Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the two-part test.

Our task is thus two-fold. First, we must determine whether the district court erred in holding that Teva failed to establish an actual controversy under Article III because it did not demonstrate that it was under **[**21]** a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent. Second, if we determine that the district court did not err in applying the law as it existed when it granted Pfizer's motion to dismiss, we must determine whether, as Teva argues, the effect of the Medicare Amendments was to establish jurisdiction in the district court over Teva's declaratory judgment action. It is to the former question that we turn first.

II.

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. *Gen-Probe, 359 F.3d at 1379*. The parties agree that the second prong (present infringing activity) of our two-part test was met by the filing of Teva's paragraph IV certification with respect to the '699 patent. The case thus turns on the first prong (reasonable apprehension of suit). Teva argues that the district court erred when it determined that Pfizer had not created a reasonable apprehension that it would bring suit against Teva for infringement of the '699 patent.

As it did in the district court, Teva places primary significance on the fact that Pfizer listed **[**22]** the '699 patent in the Orange Book, thereby representing that the patent "could reasonably be asserted" against any generic sertraline product. Teva takes the position that the requirements of the reasonable apprehension prong of the two-part test are satisfied in virtually every case in which: (1) the NDA applicant has **[*1333]** listed a patent in the Orange Book; (2) a generic manufacturer has submitted an ANDA which includes a paragraph IV certification for a drug covered by that patent; and (3) the NDA-holder or patentee has not brought an infringement suit within 45-days of receiving notice of the paragraph IV certification. Teva asserts that the only way a patentee in Pfizer's situation can defeat jurisdiction over an ANDA filer's declaratory judgment action is by affirmatively representing that it will not sue the filer.

Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced. The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, Pfizer's compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement **[**23]** intentions are concerned. The Orange Book is a listing of patents with respect to which claims of infringement "could be reasonably asserted ...." *21 U.S.C. § 355(b)(1), (c)(2)*(emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however. See *Capo, Inc. v. Dioptics Med. Prods., 387 F.3d 1352, 1355 (Fed. Cir. 2004)* ("More is needed than knowledge or notice of an adversely held patent. ... The standard is objective, and focuses on whether the patentee manifested the intention to enforce the patent, and would be reasonably expected to enforce the patent against the declaratory plaintiff." (citations omitted)). We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

In support of its contention that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent, Teva also points to Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue. We have stated

that, "[w]hen the defendant's conduct, **[**24]** including its statements falls short of an express charge, one must consider the 'totality of the circumstances' in determining whether that conduct meets the first prong of the test." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 736 (Fed. Cir. 1988)* (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987))*. Although relevant to the analysis, neither of the factors upon which Teva relies is dispositive in this case. See *BP Chems., 4 F.3d at 980* ("Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive." (internal cit ation omitted)); *Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985)* ("The prior patent litigation initiated by Semi-Alloys in 1975, against two other parties unconnected with Indium, was too remote to make Indium's apprehension of further litigation in 1982 reasonable ....").

In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of imminent suit. **[**25]** Whether there is an "actual controversy" between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty, 312 U.S. at 273*. This requirement of imminence reflects the Article III mandate that the injury in fact be "concrete," and "actual or imminent, not conjectural or hypothetical." *Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 101, 140 L. Ed. 2d 210, 118 S. Ct. 1003 (1998)*. Significantly, Teva virt ually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. **[*1334]** According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination, either of which would trigger Ivax's 180-day exclusivity period before Ivax is in a position to take advantage of the period by beginning commercial marketing of its generic sertraline drug upon expiration of the '518 patent. In any event, Pfizer need not sue Teva immediately, because Teva will not be able to receive FDA approval for its generic sertraline **[**26]** drug prior to the expiration of Ivax's 180-day exclusivity period, which will not begin until expiration of the *'518 patent* on June 30, 2006. Because Teva is unable to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent, we cannot say that the district court erred in its application of the two-part test for determining whether an actual controversy exists in a patent infringement action.

III.

Teva also argues, however, that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the traditional two-part test. Although the Medicare Amendments were not in place when this case was before the district court, Congress provided that the provisions dealing with declaratory judgments would "apply to any proceeding ... that is pending on or after the date of the enactment of this Act regardless of the date on which the proceeding was commenced ...." Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1101(c)(1), 117 Stat. at 2456. Since the district court did not issue its opinion until December 8, 2003, the date the Medicare Amendments were enacted, the declaratory **[**27]** judgment provisions apply to this case.

The Medicare Amendments amended *35 U.S.C. § 271(e)(5)*(so that it reads as follows:

> Where a person has filed an application described in paragraph (2) that includes a ce

> rtification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act *(21 U.S.C. 355),* and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5) (Supp. 2004). Thus, the Amendments explicitly state **[**28]** that an ANDA filer who submits a paragraph IV certification with respect to a patent listed in the Orange Book may, "consistent with the Constitution," bring a declaratory judgment action with respect to the patent if the patent owner does not bring an infringement action within the statutory forty-five day n7 period.

> n7 Prior to the Medicare Amendments, there was no prohibition against an ANDA filer bringing a declaratory judgment action upon expiration of the forty-five day period.

Teva argues that, in view of the Medicare Amendments, its declaratory judgment suit presents a justiciable controversy under Article III. In making this argument, Teva starts from the premise that, in its words, the reasonable apprehension **[*1335]** test serves "primarily prudential not constitutional concerns." (Br. for Teva at 52.) It then posits that, in the Medicare Amendments, Congress directed courts to exercise jurisdiction over declaratory judgment actions such as this to the limits of Article III. Joined by Amicus Curiae the **[**29]** Federal Trade Commission ("FTC"), Teva urges that it has suffered injury independent of the threat of an infringement suit because the 180-day exclusivity period itself has major economic consequences in the case of a drug such as Zoloft tm. Teva and the FTC argue that there is a clear connection between this injury and actions already taken by Pfizer. They contend that if Pfizer had not obtained the '699 patent and listed it in the Orange Book, settled its litigation with Ivax, declined to sue Teva, and refused Teva's request for a covenant not to sue, Teva would have the opportunity to gain access to the Zoloft tm market during the 180-day period that will follow the expiration of the '518 patent.

As a preliminary matter, we do not agree with Teva that the reasonable apprehension of suit test represents a prudential rule rather than a constitutional requirement. In EMC, we squarely stated that we developed the two-part inquiry, of which the reasonable apprehension of suit test is one of the parts, "to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity." *89 F.3d at 811*. Teva, nevertheless, points **[**30]** to statements in several of our cases that it argues demonstrate that the test is, in fact, merely a prudential rule. See *Arrowhead, 846 F.2d at 736* (stating that the two-part test is a "test often useful in evaluating complaints for declaratory judgments in patent cases"); *Fina Oil Chem. Co. v. Ewen, 123 F.3d 1466, 1470 (Fed. Cir. 1997)* ("Satisfaction of the

traditional two-part test is not ... a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement."); *Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1327 (Fed. Cir. 1998)* (stating that the two-part test "contributes to policing the boundary between a constitutional controversy ...and 'a difference or dispute of a hypothetical or abstract'" character. (citation omitted)).

We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our **[**31]** traditional two-part test is not a constitutional requirement. First, there is nothing in Arrowhead that supports that proposition. In Arrowhead, the court made clear that although the "actual controversy" test in suits requesting a declar ation of patent noninfringement or invalidity has been stated in various ways depending on the particular facts at hand, "the test requires two core elements: (1) acts of defendant indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement." *Arrowhead, 846 F.2d at 737*. At the same time, the statement from Fina Oil upon which Teva relies follows the court's recognition of the traditional two-part test. *123 F.3d at 1470*. Under these circumstances, the statement at most suggests that the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met. n8 The statement in no way suggests **[*1336]** that the traditional test does not address the Article III requirement of an actual case or controversy. Finally, the statement Teva quotes from *Hunter Douglas, 153 F.3d at 1327,* **[**32]** is really just another way of saying what we said in EMC in expounding on the traditional two-part test: "This court's two-part test for declaratory judgment jurisdiction is designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be deemed a controversy." *89 F.3d at 811*. We would only add that we think this case presents just the sort of situation to which the EMC court alluded: Pfizer and Teva certainly have adverse interests. However, for a variety of reasons, their adverse interests have not ripened into an actual controversy.

N8 In Fina Oil, the plaintiff sought a declaration that the inventors were properly named on the patent at issue in accordance with *35 U.S.C. § 116 (1994)*. The statement relied upon by Teva merely reflects that the precise formulation of the constitutional inquiry may vary depending on the facts of a given case.

[33]**

Neither do we think that in the Medicare Amendments Congress intended to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch-Waxman s etting. The plain language of the amended statute-that courts shall have subject matter jurisdiction "to the extent consistent with the Constitution" - compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as Teva's. The legislative history of the Medicare Prescription Drug, Improvement, and Modernization Act supports this view. In the version of the legislation originally introduced in the Senate (S. 1) in the 108th Congress, it was provided that the filing of a paragraph IV certification, and the failure of the patentee or

NDA-holder to bring an infringement action within forty-five days after the receipt of notice,

> shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under *section 2201* of title 28 for a declaratory judgment that any patent that is the subject of the **[**34]** certification is invalid or not infringed.

Thus, as introduced, the legislation would have embodied the concurring opinion of Judge Gajarsa in *3M v. Barr Labs., Inc., 289 F.3d 775, 784 (Fed. Cir. 2002)*. Judge Gajarsa suggested that "the two acts of (1) a patentee listing a patent in the Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement." *Id. at 791*. However, after changes made in conference, the legislation that became law in the 108th Congress (H.R. 1) did not contain language automatically conferring subject matter jurisdiction in the district courts anytime a patent is listed in the Orange Book, a paragraph IV certification is filed with respect to the patent, and a patentee fails to bring suit for infringement within forty-five days of receipt of notice of the certification.

The Conference Committee Report on H.R. 1 states as follows:

> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to **[**35]** delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.
>
> Through the modifications in this Act, the conferees do not intend for the **[*1337]** courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e. g., *Fina Oil and Chemical Co. v. Ewen, 123 F.3d 1466, 1471 (Fed. Cir. 1997)*. The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.
>
> In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., *Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002)*. **[**36]** n9 In any given case, the conferees expect a court may or may not

find a reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391 at 836 (2003).

n9 In Vanguard Research, while the patentee, Peat, had not made an express threat of litigation, it had (1) sought to enjoin the potential infringer, Vanguard, from production of the potentially infringing technology by filing suit against it on other grounds, (2) had written Vanguard a letter indicating that it no longer had the right to market the potentially infringing technology, and (3) had contacted the U.S. Army and Congress implying to them that Vanguard was using Peat's technology without Peat's permission. *304 F.3d at 1254*. The court held that, based on the totality of circumstances, there was a reasonable apprehension of suit on the part of Vanguard.

We conclude that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not **[**37]** intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. Our traditional two-part test remains good law, and, as discussed above, we see no error in the district court's applicat ion of the test.

Teva nevertheless points to the statement in the Conference Committee Report that "the conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act." According to Teva, making the declaratory judgment inquiry turn on the imminence of an infringement suit renders the test subject to manipulation by the patentee, thereby undermining the goals of the Hatch-Waxman Amendments to resolve patent disputes promptly once the issues are joined by the listing of a patent in the Orange Book and the serving of a paragraph IV certification with respect to the patent. Teva argues that these goals are not being served in this case. Teva points out that in view of Pfizer's settlement with Ivax, it is in Pfizer's interest to not expose the '699 patent to litigation, because doing so **[**38]** would raise the possibility of a determination of invalidity or non-infringement, either of which might trigger the commencement of Ivax's 180-day exclusivity period before the expiration of the '518 patent, in which event the exclusivity period would be useless. Teva asserts, for example, that if Pfizer can avoid triggering Ivax's 180-day exclusivity period until the expiration of the '518 patent, it can expect to enjoy six months selling Zoloft tm with only one, royalty-paying generic competitor, Ivax. At the same time, if the '699 patent were held invalid or not infringed, it would mean that during the six-month period following the expiration of the '518 patent on June 30, 2006, Pfizer would face competition in the Zoloft tm market, not only from Ivax, but from other generic manufacturers as well. These circumstances, **[*1338]** Teva urges, constitute injury to it, because the effect of Pfizer's not bringing suit against Teva is to prevent Teva from challenging the '699 patent and thereby possibly opening the door to its being able to sell generic sertraline hydrochloride during the 180-day exclusivity period following expiration of the '518 patent.

With these same considerations in **[**39]** mind, the FTC states that "while in a 'classic patent declaratory judgment suit, 'the ordinary two-part test is appropriate" (Br. for FTC at 17 (quoting *Fina Oil, 123 F.3d at 1470*)), a case such as the present one presents a different situation: "[I]n the Hatch-Wax man regime, a subsequent ANDA applicant may

suffer direct legal injury and require judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents within the regulatory scheme." (Br. for FTC at 17-18.)

We are not persuaded by Teva's and the FTC's arguments. Whether an actual controversy exists between Teva and Pfizer turns on the reasonable apprehension of suit test, which remains in place under the Medicare Amendments, and we have concluded that, under that test, Teva has not established that an actual controversy exists between it and Pfizer. The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct **[**40]** from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.

If it is the view of Congress that the 180-day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch-Waxman Amendments accordingly. Until it does so, however, we must apply the statutory scheme as written. See *Reid v. Dep't of Commerce ,793 F.2d 277, 284 (Fed. Cir. 1986)* ("'The remedy for any dissatisfaction with the results in a particular case lies with Congress' and not this court, 'Congress may amend the statute; we may not.'" (quoting *Griffin v. Oceanic Contractors, Inc., 458 U.S. 564, 576, 73 L. Ed. 2d 973, 102 S. Ct. 3245 (1982)))*. Thus, it is not for us to address any perceived inequities in the statutory scheme by eliminating the reasonable apprehension of suit test in Hatch-Waxman cases. That is what we would have to do in order to rule in favor of Teva in this case. That **[**41]** is because, in order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage vis-a-vis Ivax. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

CONCLUSION

For the foregoing reasons, we agree with the district court that Teva failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, *28 U.S.C. § 2201(a)*. We therefore affirm the court's dismissal of Teva's declaratory judgment suit for lack of jurisdiction.

[*1339] AFFIRMED

DISSENTBY: MAYER

DISSENT: MAYER, Circuit Judge*, dissenting.

* Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

Because **[**42]** the filing of a New Drug Application (NDA) and subsequent listing of a pharmaceutical patent in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") is conduct giving rise to a reasonable apprehension that an Abbreviated New Drug Application (ANDA) filer and declaratory judgment plaintiff will

face a patent infringement suit, I respectfully dissent.

I.

Our traditional two-part test to determine whether an actual controversy exists in a patent infringement suit requires that "(1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the patentee will bring suit if the activity in question continues." *Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1470 (Fed. Cir. 1997)*. Under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at *21 U.S.C. § § 355*, *360cc*, and *35 U.S.C. § 156*, *271*, *282*), **[**43]** part one is satisfied in every instance where an ANDA is filed in accordance with *21 U.S.C. § 355(j)*, because *35 U.S.C. § 271(e)(2)* provides that such a filing constitutes an act of infringement

the traditional two-part test as "often **[**44]** useful in evaluating complaints for declaratory judgments" but not mandatory in every instance). We have clarified that the "[s]atisfaction of this traditional two-part test is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement." *Fina Oil, 123 F.3d at 1470*.

Regardless of whether the two-part test is a constitutional necessity or not, the legislative history voices Congress' intent to apply the "reasonable apprehension" portion of the test in determining whether a court may determine the rights of an ANDA filer seeking relief. See H.R. Conf. Rep. No. 108-391, at 836 (2003) ("Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article

"actual controversy" existed under the Declaratory Judgment Act because, it concluded, Teva faced no "reasonable apprehension" that Pfizer would bring suit against it for infringing the '699 patent. *Teva Pharms. USA, Inc. v. Pfizer, Inc., 2003 U.S. Dist. LEXIS 21940, No. 03-CV-10167, 2003 WL 22888848 (D. Mass. Dec. 8, 2003)*.

The 2003 amendments to the Hatch-Waxman Act provide for declaratory relief when an owner of a patent listed in the Orange Book fails to bring an infringement suit within 45 days after the ANDA is filed. Medicare Prescription Drug, Improvement, **[**46]** and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("Medicare Amendments") (codified in pertinent part at *21 U.S.C. § 355(j)(5)(C)(i)*). These Medicare Amendments also give courts the authority to exercise jurisdiction over declaratory judgment actions brought by generic infringers "to the extent consistent with the Constitution." *35 U.S.C. § 271(e)(5) (2003)*.

The Declaratory Judgment Act authorizes declaratory relief only in a "case of actual controversy." *28 U.S.C. § 2201 (2000)*. This requirement is the same as the "case or controversy" requirement of Article III of the Constitution. See *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1053 (Fed Cir. 1995)* ("The purpose of the declaratory action is to permit a threatened party to resolve its potential liability, but only when the relationship has progressed to an actual controversy, as required by Article III of the Constitution."). The Supreme Court has long held "that whatever else the 'case or controversy' requirement embodied, its essence is a requirement **[**47]** of 'injury in fact. '" *Schlesinger v. Reservists Comm. to Stop the War, 418 U.S. 208, 218, 41 L. Ed. 2d 706, 94 S. Ct. 2925 (1974)* (citation omitted).

The Supreme Court also has established criteria for evaluating whether a case passes the constitutional threshold of being a "case or controversy." In *Nashville, Chattanooga & St. Louis Railway Co. v. Wallace, 288 U.S. 249, 259, 77 L. Ed. 730, 53 S. Ct. 345 (1933)*, the Court determined that it should "look not to the label which the Legislature has attached to the procedure followed in the state courts, or to the description of the judgment which is brought here for review, in popular parlance, as 'declaratory, 'but to the nature of the proceeding which the statute authorizes, and the effect of the judgment rendered upon the rights which the appellant asserts." Similarly, the Court in Aetna Life Insurance Co. v. Haworth decided that the federal Declaratory Judgment Act validly conferred jurisdiction on federal courts to issue declaratory judgments in appropriate cases. *300 U.S. 227, 81 L. Ed. 617, 57 S. Ct. 461 (1937)*. The Court "observed that the controversy would admit 'of specific relief through a decree of a conclusive character, **[**48]** as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Calderon v. Ashmus, 523 U.S. 740, 746, 140 L. Ed. 2d 970, 118 S. Ct. 1694 (1988)* (quoting *Aetna, 300 U.S. at 241*). Important to this case, the Court has "thus recognized the potential for declaratory **[*1341]** judgment suits to fall outside the constitutional definition of a 'case' in Article III: a claim 'brought before the court(s) for determination by such regular proceedings as are established by law or custom for the protection or enforcement of rights, or the prevention, redress, or punishment of wrongs. '" Id. (quoting *Fairchild v. Hughes, 258 U.S. 126, 129, 66 L. Ed. 499, 42 S. Ct. 274 (1922)*). Such is the scheme created by the jurisdictional directives of Congress in the enactment of Hatch-Waxman and corresponding Medicare Amendments - the key issue being whether the courts are capable of achieving a final or conclusive

determination that resolves the entire case or controversy.

Finding an actual controversy within the meaning of the Declaratory Judgment Act requires an analysis of the totality of the circumstances of each case. *Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376, 1379 (Fed. Cir. 2004)*. **[**49]** The facts alleged must show a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Id. "Although the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required." *Vanguard Research, Inc. v. PEAT, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002)* (citations omitted). Determining whether a reasonable apprehension of suit exists in a case controlled by the statutory and regulatory scheme of Hatch-Waxman requires a thorough analysis of the consequences and repercussions of each party's actions.

The most important basis for finding a reasonable apprehension of suit is Pfizer's listing of the '699 patent in the Orange Book. Pfizer's listing constituted an affirmative representation to the FDA and to competitors that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of any generic sertraline hydrochloride drug covered by the claims of the '699 patent. *21 U.S.C. § 355(b)(1) (2003)*. **[**50]** Although the listing in the Orange Book is a standard requirement for filing a NDA, it is a requirement that expresses a party's future intent to enforce its patent rights against those who subsequently file an ANDA and infringe. We have explained that the "reasonable apprehension" test serves to "protect[] quiescent patent owners against unwarranted litigation." *Arrowhead, 846 F.2d at 736*. Pfizer is not a defendant that "has done nothing but obtain a patent." Id. By listing its patent in accordance with *21 U.S.C. § § 355(b)(1) & (c)(2)*, Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires.

In evaluating whether there is a controversy, courts must take into account the injury that a generic drug manufacturer suffers when, as a result of actions taken by the brand-name manufacturer, it is delayed from marketing its product. Hatch-Waxman establishes that the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible, in some situations, for 180 days of marketing exclusivity, during which the FDA may not approve **[**51]** subsequent ANDAs for other generic versions of the drug. *21 U.S.C. § 355(j)(5)(B)(iv)*. Under the 1984 version of the Act, the 180-day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant; or (ii) a "decision of a court ... holding the patent which is the subject of the [Paragraph IV certification] to be invalid or not infringed." Id. *§ 355(j)(5)(B)(iv)(I-II)*. A court decision has been defined to include any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment **[*1342]** or otherwise. See *3M v. Barr Labs., Inc., 289 F.3d 775, 778 (Fed. Cir. 2002)*. If the first ANDA applicant triggers the 180-day period and promptly brings its product to market, then it is permitted, for 180 days, to be the only generic competitor for the name-brand drug. If, instead, a subsequent ANDA applicant triggers the 180-day period by obtaining a court decision, and the first ANDA applicant does not market its drug during that period, then the FDA may approve subsequent ANDAs, and the first ANDA applicant receives no exclusivity.

Although **[**52]** Congress' intention was for Hatch-Waxman to promote competition and speed generic entry into the market, the opposite has occurred as a result of strategies

to "park" the 180-day period. Brand-name drug manufacturers may enter into an agreement with the first ANDA applicant whereby the first ANDA applicant agrees to refrain from entering the market for some period of time if the brand-name firm forgoes suing subsequent ANDA applicants during the statutory 45-day period. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until: (i) 180 days after the first ANDA applicant enters; (ii) the relevant patent expires; or (iii) a subsequent ANDA applicant can itself trigger the 180-day period. Essentially, the framework of Hatch-Waxman, combined with the conduct of the brand-name manufacturer, creates a cognizable injury to the subsequent generic ANDA filer. The delay created directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market. The only way to eliminate this problem is for the subsequent ANDA applicant to bring a declaratory judgment action seeking a court decision of invalidity or noninfringement of the **[**53]** relevant patent.

Taking into account the specific regulatory context of the Hatch-Waxman regime, the "reasonable apprehension" test applied "to the extent consistent with the Constitution" is satisfied by Pfizer's conduct. See H.R. Conf. Rep. No. 108-391, at 836 (2003) ("[A] declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction" and the courts should "examine as part of their analysis the particular policies served by the Hatch-Waxman Act."). Cases arising under Hatch-Waxman do not present a classic patent declaratory judgment suit, and accordingly, the reasonable apprehension test should not be applied in the traditional manner. See *Fina Oil, 123 F.3d at 1470* (discussing classic patent declaratory judgment suits). Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In contrast, within the Hatch-Waxman regime, a subsequent ANDA applicant is not free to market - the applicant may suffer direct legal injury and require judicial relief based on the ramifications of actions that a brand-name drug manufacturer **[**54]** has already taken concerning its patents and the likelihood of a future patent suit after the running of the 180-day period.

Against the backdrop of Hatch-Waxman, the totality of Pfizer's conduct must also be considered. See H.R. Conf. Rep. No. 108-391, at 836 (2003) ("In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where [an ANDA has been filed with a Paragraph IV certification and the patentee has not brought an infringement suit within 45 days]."). First, Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride. This shows both Pfizer's belief that its '699 patent is valid and its intent to assert the patent against infringers. "Related litigation may be evidence of a reasonable apprehension." *Shell Oil Co. v. Amoco Oil Co., 970 F.2d 885, 888* **[*1343]** *(Fed. Cir. 1992)*. Pfizer also has a history of asserting its patent rights against infringers of other patents. Considering that the '699 patent, which covers the brand name drug Zoloft tm ,produced nearly 3 billion dollars in profit in 2002, economics and common sense dictate that Pfizer may well bring suit. Finally, Pfizer refused to grant Teva **[**55]** a covenant not to sue for infringement of the '699 patent.

Allowing Teva's declaratory judgment action is consistent with the "case or controversy" requirement of Article III of the Constitution because the suit will achieve a final determination that resolves the entire controversy between Teva and Pfizer. Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a

generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief. Consequently, under the Hatch-Waxman regime, Teva's injuries are traceable to Pfizer's conduct and those injuries could be redressed by a favorable decision. Therefore, Teva maintains a reasonable apprehension of suit sufficient to confer jurisdiction under the Declaratory Judgment Act.

EXHIBIT 3

LEXSEE 2004 U.S. DIST. LEXIS 11930

TORPHARM, INC., APOTEX CORP. and APOTEX, INC., Plaintiffs, v. PFIZER INC. and WARNER LAMBERT COMPANY (n/k/a WARNER-LAMBERT LLC), Defendants.

Civ. No. 03-990-SLR

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2004 U.S. Dist. LEXIS 11930

June 28, 2004, Decided

DISPOSITION: **[*1]** Defendants' motions to dismiss granted.

LexisNexis(R) Headnotes

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JUDGES: Sue L. Robinson, United States District Judge.

OPINIONBY: Sue L. Robinson

OPINION:

MEMORANDUM OPINION

Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On October 29, 2003, plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. filed a declaratory judgment action against defendants Pfizer Inc. and Warner-Lambert Company. Plaintiffs seek a declaration that their generic version of Pfizer's patented drug Accupril(R) will not infringe *U.S. Patent No. 4,743,450* ("the '450 patent"). (D.I. 1) On February 23, 2004, plaintiffs filed an **[*2]** amended complaint to provide additional information about the statutory scheme for the approval of generic drugs. (D.I. 18)

Plaintiff TorPharm is incorporated under the laws of Canada with its principal place of business in Etobicoke, Ontario, Canada. (D.I. 1 at P 5) TorPharm develops, manufactures, and markets generic drugs, in particular solid oral dosage forms, such as capsules and tablets, for sale and use in the United States. (Id.) Plaintiff Apotex Corp. is incorporated under the laws of the State of Delaware with its principal place of business in Lincolnshire, Illinois. (D.I. 1 at P 6) Apotex is the United States marketing and sales affiliate for TorPharm. (Id.) Plaintiff Apotex, Inc. is incorporated under the laws of Canada with its principal place of business in Weston, Ontario, Canada. (Id. at P 7) Defendant Pfizer Inc. is organized under the laws of the State of Delaware with its principal place of business in New York, New York. (Id. at P 9) Defendant Warner-Lambert LLC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in Morris Plains, New Jersey. n1 (D.I. 1 at P 10)

n1 As of June 19, 2000, Warner-Lambert Company became a wholly owned subsidiary of defendant Pfizer Inc.. Warner-Lambert Company subsequently became Warner-Lambert LLC. (Id. at P 10)

[*3]

On January 8, 2004 and April 1, 2004, defendants filed motions to dismiss the complaint and the amended complaint, respectively, for lack of subject matter jurisdiction pursuant to *Fed. R. Civ. P. 12(b)(1)*. (D.I. 8, 20) These motions are presently before the court. For the reasons to follow, the court grants both motions.

II. BACKGROUND

A. Regulatory Approval for Brand Drugs

Under the *Federal Food, Drug, and Cosmetic Act* ("FFDCA"), an innovator pharmaceutical company ("innovator") who seeks to manufacture a new brand drug is required to file a new drug application ("NDA") with the Federal Food and Drug Administration ("FDA"). *21 U.S.C. § 355(a)*. Submitting an NDA is frequently a time-intensive and costly process because, among other things, the NDA must contain detailed clinical studies of the brand drug's safety and efficacy. The NDA also must include a list of patents which claim the brand drug:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such **[*4]** drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug... . Upon approval of the application, the Secretary shall publish information submitted under [this section].

21 U.S.C. § 355(b)(1). If the FDA approves an NDA, then it publishes, or "lists," information about the brand drug and patents covering the brand drug's approved aspects in a publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." Id.

B. Regulatory Approval for Generic Drugs

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at *21 U.S.C. § § 355*, *360cc* and *35 U.S.C. § § 156*, *271*, *282*, n2 a generic drug manufacturer ("generic") who seeks approval to market a generic version of a previously approved brand drug may submit an abbreviated new drug application ("ANDA") to the FDA. n3 *21 U.S.C. § 355(j)*. In the ANDA, a generic

may rely on the safety and efficacy **[*5]** studies previously submitted to the FDA in the innovator's NDA by showing the generic drug's bioequivalence with the previously approved brand drug. *21 U.S.C. § 355(j)(2)(A)*. The generic also must "certify" whether the generic drug would infringe the patent(s) listed in the Orange Book for the brand drug. *21 U.S.C. § 355(j) (2) (A) (vii)*. To satisfy this requirement, a generic may make one of four possible certifications for each patent claiming either the listed brand drug or the use of the listed brand drug: (I) that no patent information on the brand drug has been submitted to the FDA; (II) that the listed patent has expired; (III) that the listed patent will expire on a stated date; or (IV) that the listed patent is invalid or will not be infringed by the generic product. *21 U.S.C. § 355(j) (2) (A) (vii) (I)-(IV)*. These options are designated as paragraph I, II, III, and IV certifications, respectively.

n2 The Drug Price Competition and Patent Term Restoration Act of 1984 is more commonly known as the "*Hatch-Waxman Act*." It amended various provisions of the FFDCA and Title 35 of the United States Code relating to patents. Title 1 of the Act was intended to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." *Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001)* (citing H.R. Rep. No. 98-857, pt. 1 at 14 (1984)). **[*6]**

n3 A generic does not commit an act of infringement in submitting an ANDA. *35 U.S.C. § 271 (e)(1)*("It shall not be an act of infringement to make, use, offer to sell, or sell ... a patented invention ... solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.").

With a paragraph I or II certification, the FDA may grant approval as soon as it is satisfied that the product is safe and effective. *21 U.S.C. § 355(j) (5) (B) (i)*. Under a paragraph III certification, the FDA may approve the ANDA as soon as the patent on the brand drug expires. *21 U.S.C. 355(j)(5)(B)(ii)*. If the generic enters paragraph III certifications for more than one patent, then the FDA may not grant approval until the last patent expires. Filing an ANDA with a paragraph IV certification presents a more unique situation; it is considered to be a "technical" or "artificial" act of infringement. *35 U.S.C. § 271(e)(2)(A)*("It shall be an **[*7]** act of infringement to submit an application under *section 505(j)* of the [FFDCA] or described in *section 505(b) (2)* of such Act for a drug claimed in a patent or the use of which is claimed in a patent."); see *Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678, 110 L. Ed. 2d 605, 110 S. Ct. 2683 (1990)*("An act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by *§ 271 (e) (2)* - the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent."). Consequently, the ANDA applicant must explain why a generic version of the previously approved brand drug would not infringe the patent covering the previously approved brand drug or why such patent is invalid. *21 U.S.C. § 355 (j) (2) (B) (i)*. In response, the patent holder has the option of filing a patent infringement action within

forty-five days after receiving such notice. *21 U.S.C. § 355(j)* **[*8]** *(5) (B) (iii)*. During this window, the generic may not file a declaratory judgment action based upon the filing of the ANDA. Id. If the patent holder fails to bring suit, then the FDA may approve the ANDA. Id. However, if the patent holder elects to bring suit, then the effective date of any FDA approval is delayed for either thirty months or until a court rules that the patent is invalid or not infringed, whichever occurs first. Id.

The first generic to file an ANDA containing a paragraph IV certification is known as a "first filer" and is eligible for a 180-day exclusivity period. This means that the first filer is entitled to have the sole generic version of the brand drug on the market for the first 180-days following the earlier of: (1) the date of the first commercial marketing of the generic drug by the first filer; or (2) a court decision of noninfringement or invalidity by any ANDA applicant in any action. *21 U.S.C. § 355(j) (5) (B) (iv)*. Any subsequent ANDA filer must wait until the expiration of this 180-day exclusivity period before the FDA will approve its ANDA. n4

> N4 If the first filer does not opt to commercially market its generic drug, then subsequent ANDA filers may trigger the 180-day exclusivity period by obtaining a court decision of noninfringement or invalidity.

[*9]

B. *The Medicare Act*

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60 (the "Medicare Act"). (D.I. 18 at P 48) Title XI of the Act, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA. (Id.) In particular, the Medicare Act amended *21 U.S.C. § 355(j) (5) (C) (i) (I) (2)* to provide that a generic who has filed a paragraph IV certification may bring a declaratory judgment action against the patent holder and/or holder of the NDA if: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the holder of the NDA brought an action for patent infringement within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The Medicare Act also amended *21 U.S.C. § 355(j)(5)(C)(i)(II)* to provide that if the above three conditions are satisfied, then

> the applicant ... may, in accordance with *section 2201* of title 28, United States **[*10]** Code, bring a civil action under such section against the [patent] owner or holder [of the NDA] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

The Medicare Act likewise added a new provision to *35 U.S.C. § 271(e)*, the section of the patent code relevant to infringement actions. This provision provides that if: (1) a generic makes a paragraph IV certification; and (2) the patent holder or holder of the NDA fails to sue the generic for patent infringement within the forty-five day window after receiving notice; then (3) "the courts of the United States shall, **to the extent consistent with the Constitution,** have subject matter jurisdiction in any action brought by such person under *section 2201* of title 28 for a declaratory judgment that such patent is invalid or not infringed." *35 U.S.C. § 271 (e) (5)* (emphasis added).

C. The Brand Drug Product

Accupril(R) is the brand name for *quinapril hydrochloride*. The FDA has approved Accupril(R) for the treatment of hypertension and for the management of heart failure. (D.I. 21 at P 4) Accupril(R) **[*11]** has been on the market in the United States since 1991. (Id.) In accordance with *21 U.S.C. § 355(b) (1)*, Pfizer listed the numbers and the expiration dates for the patents covering either Accupril(R) tablets or a method of using those tables with the FDA. (Id.) The FDA, in turn, published this information in the Orange Book. (Id.) The '450 patent is one of the patents found in the Orange Book; it expires on February 24, 2007. (Id.)

D. The First Filer

At a date prior to January 15, 1999, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with paragraph IV certification directed to *quinapril hydrochloride*. (D.I. 22 at P 2) Teva asserted that the '450 patent is invalid. n5 On January 15, 1999, Teva notified defendant Warner-Lambert of this filing. (Id.) Within forty-five days thereafter, defendant Warner-Lambert filed an action against Teva for infringement of the '450 patent in the United States District Court for the District of New Jersey. (Id. at P 4; D.I. 26 at 11) On October 2, 2003, the District of New Jersey held that Teva infringes the '450 patent and granted summary judgment in favor of Pfizer on this ground. See **[*12]** *Warner-Lambert Co. v. Teva Pharms. USA, 289 F. Supp. 2d 515, 545 (D. N.J. 2003)*. n6 The parties have yet to litigate the issues of validity and enforceability. (D.I. 22 at P 5)

n5 The FDA approved Teva's ANDA on May 30, 2003. (D.I. 21 at 7)

n6 After receiving this favorable decision, defendants issued a press release commenting on the ruling. Defendants' senior vice president and general counsel stated: "[Defendants] [are] pleased with the court's summary judgment decision because it affirms positions the company has maintained with respect to the Accupril(R) patent from the very beginning of the litigation ... [Defendants] will continue aggressively to defend challenges to its intellectual property." (D.I. 21, ex. D)

As the first filer, Teva is entitled to a 180-day period of generic exclusivity from the earlier of: (1) the date it first commercially markets generic *quinapril hydrochloride;* or (2) the date of a court decision declaring the '450 patent invalid. See *21 U.S.C. § 355* **[*13]** *(j)(5)(B)(iv)(I), (II)*. To date, neither event has occurred. If Teva prevails in its litigation against Warner-Lambert and the District of New Jersey declares the '450 patent invalid, then the clock will start running on Teva's 180-day exclusivity period. Other generics who receive FDA approval will be able to begin marketing their generic versions of *quinapril hydrochloride* upon expiration of Teva's period of exclusivity.

E. Plaintiffs' ANDA

On September 13, 2001, plaintiffs filed an ANDA seeking approval to market its own generic version of *quinapril hydrochloride*. (D.I. 18 at P 62) Plaintiffs entered a paragraph IV certification with respect to the '450 patent. (Id. at P 64) Around November 15, 2001, plaintiffs notified defendants about the ANDA filing and the paragraph IV certification pursuant to *21 U.S.C. 355(j)(2)(B)(iv)*. (Id. at P 67) Defendants did not file a patent infringement action asserting the '450 patent against plaintiffs within forty-five days of receiving this notice. (D.I. 22 at P 6) On February 3, 2004, plaintiffs sent a letter to defendants offering confidential access to their ANDA. (D.I. 18 at P 69; D.I. 21, ex. **[*14]** G)

F. Other ANDAs Directed to *Quinapril Hydrochloride*

Besides Teva and the plaintiffs at bar, eight other generics have filed ANDAs seeking approval to market generic *quinapril hydrochloride* between January 2001 and May 2003. n7 These generics include: (1) Geneva Pharmaceuticals, Inc; (2) Andrx Pharmaceuticals, Inc.; (3) Par Pharmaceuticals, Inc.; (4) Ivax Pharmaceuticals, Inc.; (5) Mutual Pharmaceutical Company, Inc.; (6) Ranbaxy Pharmaceuticals Inc.; (7) Amide Pharmaceutical, Inc.; and (8) Mylan Pharmaceuticals Inc.. (D.I. 22 at P 7) Pfizer has not initiated litigation against any of these eight companies in connection with their ANDAs. (Id.)

n7 Though not specifically stated by the parties, the court presumes that each of these generics included paragraph IV certifications in their ANDA filings based upon the parties' representations about these filings.

III. STANDARD OF REVIEW

"Federal courts are courts of limited jurisdiction. They possess only that power authorized by the **[*15]** Constitution and statute ... It is to be presumed that a cause lies outside this limited jurisdiction and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. Of Am., 511 U.S. 375, 377, 128 L. Ed. 2d 391, 114 S. Ct. 1673 (1994)*(citations omitted). A subject matter jurisdiction attack under *Fed. R. Civ. Pro. 12(b)(1)*, therefore, challenges the court's jurisdiction to address the merits of the complaint. See *Lieberman v. Delaware, 2001 U.S. Dist. LEXIS 13624, 2001 WL 1000936, at *1 (D. Del. 2001)*. A party may raise the lack of subject matter jurisdiction at any time; it cannot be waived. *Fed. R. Civ. P. 12(h)(3)*. In fact, the court is obliged to address the issue on its own motion, if not raised by the parties. See *Neiderhiser v. Berwick, 840 F.2d 213, 216 (3d Cir. 1988)*. Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. See *Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc., 227 F.3d 62, 69 (3d Cir. 2000)*.

Under *Rule 12(b)(1)*, the court's **[*16]** jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *Mortensen v. First Fed. Sav. & Loan, 549 F.2d 884, 891 (3d Cir. 1977)*. Under a facial challenge, the court must accept as true the allegations contained in the complaint. See 2 James W. Moore, Moore's Federal Practice § 12.30 [4] (3d ed. 1997). Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or ... is wholly insubstantial and frivolous.'" *Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1408-1409 (3d Cir. 1991)* (quoting *Bell v. Hood, 327 U.S. 678, 682, 90 L. Ed. 939, 66 S. Ct. 773 (1946)*).

Under a factual attack, however, the court is not "confined to allegations in the ... complaint, but [may] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States, 36 V.I. 392, 115 F.3d 176, 179 (3d Cir. 1997)*; see also *Mortensen, 549 F.2d at 891-892*. "No presumptive truthfulness **[*17]** attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group, 227 F.3d at 69* (quoting *Mortensen, 549 F.2d at 891*). Because defendants did not answer either plaintiffs' original complaint or their amended complaint, the court shall treat the instant

subject matter jurisdiction challenge as a facial attack.

IV. DISCUSSION

A. The Legal Standard for Declaratory Judgment

The Declaratory Judgment Act states in pertinent part:

> In a case of actual controversy within its jurisdiction, ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201(a). Under this act, a court may declare the rights and other legal relations of any interested party only where there exists an "actual **[*18]** controversy." *Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999)*. This requirement effectuates Article III of the Constitution, which authorizes the federal judiciary to hear justiciable cases and controversies. n8 See *EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996)*.

> n8 The Supreme Court has held that Article III is satisfied where there is: (1) an actual or imminent injury-in-fact; (2) that is fairly traceable to the defendant; and (3) is redressible by a favorable decision. *Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561, 119 L. Ed. 2d 351, 112 S. Ct. 2130 (1992)*.

To guide the case-or-controversy analysis in patent-based declaratory judgment suits, the Federal Circuit has developed a two-part test. "For actual controversy to exist, 'there must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit; and **[*19]** (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.'" *Amana, 172 F.3d at 855* (quoting *BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993)*). The burden is on the declaratory judgment plaintiff "to establish that jurisdiction over its declaratory judgment action existed at, and has continued since, the time the complaint was filed." *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575 (Fed. Cir. 1986)*. "Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp, 89 F.3d at 810*.

The first prong looks to the patent holder's conduct. *BP Chems. Ltd., 4 F.3d at 978*. If a defendant expressly charges that a plaintiff's current activity constitutes infringement, then there is an actual controversy. *Arrowhead Indus. Water v. Ecolochem, 846 F.2d 731, 736 (Fed. Cir. 1988)*. In light of the subtleties in lawyer language, however, courts have not **[*20]** required an express infringement charge. Id. (citing *Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 956 (Fed. Cir. 1987)*). When the defendant's conduct, including its statements, falls short of an express charge, the court must consider the "totality of the circumstances" in determining whether the defendant's conduct meets the first prong of the test. *Arrowhead, 846 F.2d at 736*. Thus, the declaratory judgment plaintiff must demonstrate "conduct

that rises to a level sufficient to indicate an intent [of the patent holder] to enforce its patent, i.e., to initiate an infringement action." *EMC Corp, 89 F.3d at 811* (citations omitted). Subjective impressions of the declaratory judgment plaintiff, however, are insufficient to satisfy the requirement. The court must find objective facts considering the totality of the circumstances at the time the complaint was filed. *Arrowhead, 846 F.2d at 736*.

The second prong looks to the potential infringer's conduct. *BP Chems. Ltd., 4 F.3d at 978*. The potential infringer must be engaged in an actual making, selling, or using activity subject to **[*21]** an infringement charge or must have made meaningful preparation for such activity. This prong insures that the declaratory judgment plaintiff has a "true interest to be protected" and prevents such plaintiff from seeking an advisory opinion on potential liability for initiating some future activity. *Arrowhead, 846 F.2d at 736*.

B. Defendants' Motion to Dismiss

1. Subject Matter Jurisdiction Pursuant to the Medicare Act

Plaintiffs argue that they are not required to satisfy the reasonable apprehension of suit requirement to confer subject matter jurisdiction pursuant to the amendments made to *21 U.S.C. § 355(j)(5)(C)(i)(II)* and *35 U.S.C. § 271(e)(5)* by the Medicare Act. (D.I. 26 at 14) Plaintiffs claim that they need only satisfy the case or controversy requirement of Article III of the Constitution. In this regard, plaintiffs contend that they have been directly injured by defendants because they cannot enter the *quinapril hydrochloride* market with their generic product until after the '450 patent expires due to the "bottleneck" that defendants created by engaging in litigation against Teva. n9 Plaintiffs maintain **[*22]** that a declaratory judgment in their favor will redress this injury as they will be able to market their generic version of *quinapril hydrochloride*. Accordingly, plaintiffs aver that the court has subject matter jurisdiction over the instant dispute.

n9 Recall that pursuant to *21 U.S.C. 355(j)(5)(B)(iv)*, the FDA cannot approve plaintiffs' ANDA until 180 days after Teva enters the market with its generic *quinapril hydrochloride* or until a favorable court decision on the '450 patent, whichever is earlier. Plaintiffs claim that Teva will not enter the market because the District of New Jersey found that its generic version of *quinapril hydrochloride* infringed the '450 patent. Plaintiffs also allege that defendants have delayed filing suit against them or any of the other subsequent ANDA filers to avoid triggering a court decision that potentially may find the '450 patent not infringed or invalid.

The court does not read the plain language of either *21 U.S.C. § 355* **[*23]** *(j)(5)(C)(i)(II)* or *35 U.S.C. § 271(e)(5)* as eliminating the Federal Circuit's two-part test. Rather, the plain language of *21 U.S.C. § 355(j)(5)(C)(i)(II)* requires a generic to satisfy three prerequisites before lodging a declaratory judgment action against a patent holder; this provision does not in any way address subject matter jurisdiction. The plain language of *35 U.S.C. § 271(e)(5)*, on the other hand, reaches the issue of subject matter jurisdiction. It requires courts to exercise subject matter jurisdiction in a patent-related declaratory judgment action "consistent with the Constitution." The court interprets this language to mean that a generic must satisfy the case and controversy requirement set forth in Article III. Given that the Federal Circuit established its two-part test to guide the case-or-controversy analysis in conformity with

Article III, the court finds that this test is "consistent with the Constitution" and applicable to the litigation at bar.

The court observes that the legislative history for the Medicare Act substantiates this interpretation. Congress specifically contemplated a continuation **[*24]** of the constitutional standard for subject matter jurisdiction, including the reasonable apprehension requirement. According to the House of Representatives conference report,

> the conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effect to delay infringement litigation between generic drug manufacturers and pioneer drug companies. **The conferees expect courts to apply the 'reasonable apprehension' test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.** Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction. The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act. In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought **[*25]** an infringement suit within the [forty-five] days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391, at 836 (2003)(citations omitted)(emphasis added). Taking this explanation together with the Federal Circuit's plain language of the Medicare Act, the court concludes that the two-part test remains as the standard for determining whether a district court has subject matter jurisdiction over a patent-based declaratory judgment action.

Turning to the facts at bar, plaintiffs were not required to comply with the three prerequisites set forth in *21 U.S.C. § 355(j)(5) (C) (i)(II)* because they filed their original complaint on October 29, 2003, approximately one month prior to the enactment of the Medicare Act on December 8, 2003. Nevertheless, the Medicare Act applies to all proceedings pending on or after December 8, 2003. As such, defendants focus on plaintiffs' amended complaint, which was filed on February 23, 2004, nearly **[*26]** three months after the Medicare Act became effective. To this end, defendants argue that plaintiffs filed their amended complaint only twenty days after offering defendants confidential access to their ANDA, well within the forty-five day period.

At the outset, the court observes that defendants confuse the prerequisites. The Medicare Act states that a declaratory judgment action may not be brought unless: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor holder of the NDA brought an action for

infringement of the patent within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The forty-five day window, therefore, relates to notice of the ANDA filing containing the paragraph IV certification, not notice of the complaint or, in the case at bar, the amended complaint. Additionally, compliance with the Medicare Act as of the date of the amended complaint is of no import; the Medicare Act seeks to ensure that a patent holder has full opportunity to consider an ANDA and decide whether to file an infringement action prior **[*27]** to being forced to stand in defense in a declaratory judgment action. This consideration occurs with the filing of an original complaint, not as of the filing of an amended complaint in a suit already in progress. Accordingly, the court declines to dismiss the instant litigation on procedural grounds.

2. Subject Matter Jurisdiction Under the Federal Circuit's Two-Part Test n10

n10 The parties dispute only the first prong of this test, to wit, whether plaintiffs were in reasonable apprehension of an infringement suit as of October 29, 2003, the date of plaintiffs' original complaint. The court, therefore, confines its analysis to this question. For sake of clarity, the court observes that plaintiffs satisfied the second prong of the two-part test, i.e., activity which could constitute infringement, by filing the ANDA. See *35 U.S.C. § 271(e)(2)*; see also *infra* Section II, A.

Plaintiffs argue that they were under a reasonable apprehension of suit at the time they filed their **[*28]** complaint based upon various actions by defendants, including the following: (1) listing the '450 patent in the Orange Book n11 (D.I. 18 at PP 27, 89); (2) failing to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent or to provide plaintiffs with a covenant not to sue (id. at P 89); (3) initiating an infringement lawsuit against Teva regarding the *'450 patent (*id. at PP 80, 81); (4) stating in a press release "that it will continue to aggressively defend challenges to its intellectual property" (id. at PP 79, 89; D.I. 21, ex. D); and (5) initiating a lawsuit against plaintiffs over a different product (Neurotin(R)), thereby showing a "pattern of aggressively enforcing its patents" against "the generic pharmaceutical industry generally." (Id. at PP 72-78, 89)

n11 Plaintiffs argue that defendants implied that an infringement action could be brought against any generic who seeks ANDA approval for a generic version of *quinapril hydrochloride* by listing the '450 patent in the Orange Book.

[*29]

Before delving into the details of plaintiffs' arguments, the court recognizes that it is often difficult to identify whether a reasonable apprehension of suit exists. This question entails a balance, similar to the balance that the Hatch-Waxman Act struck between innovators and generics. On the one hand, a patent owner should not be dragged into court when it has not engaged in threatening or aggressive acts simply because it chooses to inform potential infringers of its patent rights. In the case of the pharmaceutical industry, an innovator has invested a tremendous amount of research effort, dollars, and time into developing and marketing a brand drug. Such innovators also have expended considerable resources in establishing a patent portfolio to protect said brand drug. The court respects both the

innovator's efforts and legitimate patent rights and does not easily dismiss these investments. On the other hand, however, the Declaratory Judgment Act was enacted to prevent patent owners from using "guerrilla-like" tactics and attempting "extrajudicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with **[*30]** uncertainty and insecurity." *Arrowhead, 846 F.2d at 735.* As well, the court is mindful that a generic should be entitled to market its generic version of a brand drug if a product does not infringe the patent listed in the Orange Book for the brand drug or said patent is invalid. In such situations, the court appreciates that a declaratory judgment action may be the only means for a generic to reach the market given the possibility for a so-called "bottleneck."

With this background in mind, the court turns to consider plaintiffs' contentions concerning the first prong of the two-part test. Plaintiffs argue that a generic, in general, is placed in a position of reasonable apprehension of litigation when it submits an ANDA because a patent holder may file a patent infringement action against it. n12 In asserting this position, plaintiffs reference the concurrence from Judge Gajarsa in *Minnesota Mining & Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775 (Fed. Cir. 2002).* Judge Gajarsa opined that

> filing an NDA application meets prong one of the declaratory judgment case or controversy requirement, because filing the application requires the patentee **[*31]** to maintain that an infringement suit could 'reasonably be asserted' against one who 'engaged in the manufacture, use or sale of the drug.' This is 'conduct giving rise to a reasonable apprehension on the plaintiff's part that it will face an infringement suit or the threat of one.'

Id. at 791 (citations omitted). n13

n12 Recall that in listing a patent in the Orange Book, a patent holder represents that a claim for infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of the drug. See *21 U.S.C. § 355(b)(1).*

n13 Similarly, the D.C. Circuit appears to share this view, stating that

> the Federal Circuit has had no occasion to decide whether there is a 'controversy of sufficient immediacy and reality' to support a declaratory judgment action, ... when the plaintiff requires a judgment under *section 355(j)(5)(B)* in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.

Mova Pharm. Corp. v. Shalala, 329 U.S. App. D.C. 341, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998).

[*32]

Judge Gajarsa's reasoning addresses the practical difficulties facing a generic in plaintiffs' situation, i.e., a generic who does not face a "reasonable apprehension of suit" but who needs a judicial determination in order to get to market. Nevertheless, absent binding precedent or further edification through legislation, the court declines to extend the well established principles governing declaratory judgment actions to cover the admittedly frustrating position occupied by plaintiffs at bar. In the first instance, defendants were required by statute to list the '450 patent in the Orange Book. In light of this obligation, the court is not convinced that defendants intended to communicate an intent to sue each and every generic who opts to file an ANDA for *quinapril hydrochloride,* contrary to plaintiffs' suggestion. The evidence of record, in fact, shows an opposite intention. To date, defendants have asserted the '450 patent only against Teva, despite at least eight other generics having filed ANDAs for *quinapril hydrochloride* with paragraph IV certifications. Additionally, our sister courts, when confronted with virtually identical facts to those at bar, have found that **[*33]** the act of listing a patent in the Orange Book does not create an "actual controversy." See *Mutual Pharm. v. Pfizer, 307 F. Supp.2d 88 (D. D.C. 2004)*; *Dr. Reddys Labs., Ltd. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 24351, 2004 WL 596106 (D. N.J. 2003)*; *Teva Pharms. USA, Inc. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 21940, 69 U.S.P.Q.2d 1791 (D. Mass. 2003)*. Indeed, the District of Massachusetts has noted that "[a] blanket reference to this effect would cover every patent holder who listed a patent, thereby eliminating the second prong of the test. A patent holder may have reasons to sue for infringement, and all things depending, reasons not to sue." *2003 U.S. Dist. LEXIS 21940, [WL] at *13*. The court, consequently, concludes that the mere listing of a patent in the Orange Book does not give plaintiffs reason to fear suit.

Plaintiffs also point out that defendants failed to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent and failed to provide them with a covenant not to sue. While the Federal Circuit previously has acknowledged that a patent holder's failure to give such an assurance is relevant to a court's jurisdictional inquiry, *BP Chems. Ltd, 4 F.3d at 980,* **[*34]** plaintiffs fail to cite evidence to demonstrate that they requested either an assurance or a covenant not to sue. Moreover, even if plaintiffs made such requests, defendants are not required under the Hatch-Waxman Act to give either an assurance or a covenant not to sue. Thus, the court declines to construe defendants' silence as conduct sufficient to suggest an intention to sue.

Plaintiffs likewise maintain that defendants' litigation history establishes a reasonable apprehension of suit. In this regard, plaintiffs call attention to fact that defendants: (1) are engaged in an ongoing infringement action against Teva regarding the '450 patent; (2) have been involved in suits against plaintiffs and at least eight other ANDA filers over Neurotin(R) for the past five years; and (3) are actively pursuing other infringement actions against various generics who sought to market generic versions of their brand drugs, including Zoloft(R), Celebrex(R), Lipitor(R), Norvasc(R), Procardia XL(R), Glucotrol XL(R), and Xalatan(R). As to plaintiffs' litigation involving the '450 patent, defendants have not sued any of the subsequent eight ANDA filers, four of whom filed ANDAs prior to plaintiffs. **[*35]** n14 Contrary to plaintiffs' characterization of this fact as "meaningless," the court finds it to be persuasive evidence that defendants are not engaged in a pattern of widespread litigation aimed at enforcing the

'450 patent against all generics interested in marketing generic *quinapril hydrochloride*. As such, the court declines to conclude that defendants' litigation efforts with respect to Teva translate into an intent to enforce the '450 patent against plaintiffs.

n14 Geneva Pharmaceuticals, Andrx Pharmaceuticals, Par Pharmaceuticals, Inc., and Ivax Pharmaceuticals, Inc. filed ANDAs seeking approval to market generic *quinapril hydrochloride* on January 9, 2001, January 25, 2001, June 1, 2001, and July 20, 2001, respectively. Plaintiffs did not file their ANDA until September 13, 2001.

The court is equally unpersuaded that defendants' Neurotin(R) litigation created a reasonable apprehension of suit. In *Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987),* **[*36]** the Federal Circuit acknowledged that a history of adverse legal interests bears upon the reasonable apprehension issue, even if the prior litigation did not involve the same patents implicated in the declaratory judgment suit. Nonetheless, the court observes that the link between the parties' adverse legal interests in *Goodyear* were much stronger than those at bar. In Goodyear, the defendant sued the plaintiff in state court over the same technology covered by the patents disputed in the declaratory judgment action. The Federal Circuit opined that, "by suing Goodyear in state court for the same technology as is now covered by the patents, [defendant] has engaged in a course of conduct that shows a willingness to protect that technology." *Id. at 956.* In contrast, defendants' Neurotin(R) litigation does not implicate the same technology as would be involved in a suit over Accupril(R). Therefore, the court finds that defendants' desire to protect their presence in the pain and seizure markets with Neurotin(R) is unrelated to their intentions as to the hypertension and heart failure markets with Accupril(R). While the parties' adverse interests remain a consideration, **[*37]** the court finds that the factual background in this case, unlike the factual background in *Goodyear,* is not such that plaintiffs had an objective reason to fear litigation.

Similarly, the court finds that defendants' litigation against third party generics, even when viewed in the aggregate with defendants' suit against Teva and their Neurotin(R) litigation, does not place plaintiffs in a reasonable apprehension of suit. (See D.I. 27, ex. B) Plaintiffs overdramatize the situation in stating "there is no end to the lengths that [defendants] will go to protect its branded monopolies through litigation." Plaintiffs' subjective beliefs do not amount to a threat or other action sufficient to prove the imminence of a lawsuit. In addition, that defendants enforced their patent rights against other generics with respect to Zoloft(R), Celebrex(R), Lipitor(R), Norvasc(R), Procardia XL(R), Glucotrol XL(R), and Xalatan(R) does not provide any indication of its intentions regarding the '450 patent and *quinapril hydrochloride.* To this end, the Federal Circuit considers whether the parties have engaged in some form of communication about the patent in dispute when analyzing the reasonable **[*38]** apprehension question. n15

n15 Notably, the Federal Circuit also has recognized that "if circumstances warrant, a reasonable apprehension may be found in the absence of any communication from defendant to plaintiff." *Arrowhead, 846 F.2d at 736.*

The Federal Circuit has cautioned:

> The test for finding a "controversy" for jurisdictional purposes is a pragmatic one and cannot turn on whether the parties use polite terms in dealing with one another or engage in more bellicose saber rattling. The need to look to substance rather than form is especially important in this area, because in many instances ... the parties are sensitive to the prospect of a declaratory judgment action and couch their exchanges in terms designed either to create or defeat declaratory judgment jurisdiction. In the end, the question is whether the relationship between the parties can be considered a "controversy," and that inquiry does not turn on whether the parties have used particular "magic words" in communicating **[*39]** with one another.

EMC Corp., 89 F.3d at 811-12. The Federal Circuit has found no apprehension of suit existed where the patent holder has made no contact with the declaratory judgment plaintiff. *West Interactive Corp. v. First Data Res., Inc., 972 F.2d 1295, 1297 (Fed. Cir. 1992)*. n16 In the case at bar, plaintiffs have not alleged any communication, either direct or indirect, from defendants concerning the '450 patent. The record also does not reveal any such communication. Moreover, the record does not show that defendants communicated with any third parties about plaintiffs or the '450 patent. As noted above, defendants have stood silent throughout the course of this litigation. The only interaction between the parties, in fact, occurred when plaintiffs initiated contact with defendants by: (1) notifying them of their ANDA with paragraph IV certification as required by *21 U.S.C. § 355 (j) (2) (B)*; and (2) sending them a letter offering confidential access to their ANDA in accordance with *21 U.S.C. § 355 (j) (5) (C) (i) (I) (2)*. Given these circumstances, plaintiffs cannot complain that they feared **[*40]** that defendants would sue them for patent infringement.

> n16 In contrast, the Federal Circuit has held the reasonable apprehension inquiry satisfied in certain situations where the defendant directly communicated with the plaintiff. See, e.g., *Sierra Applied Scis. Inc. v. Advanced Energy Indus., 363 F.3d 1361, 1374 (Fed. Cir. 2004)* (concluding that letters from defendant to plaintiff expressly charging plaintiff with patent infringement were sufficient to establish a reasonable apprehension); *EMC Corp., 89 F.3d at 812* (finding a letter from defendant to plaintiff referencing "'turning the matter over to'" plaintiff's litigation counsel "' for action'" and urging a "'preliminary business discussion,'" "'perhaps avoiding this matter escalating into a contentious legal activity[,]'" to be the "most telling evidence" of reasonable apprehension).

Finally, defendants' press release statement that they "will continue aggressively to defend challenges to [their] intellectual property" **[*41]** is not sufficient to instill a reasonable apprehension of suit. Defendants' statement, even though made in the context of discussing the infringement suit against Teva, is of a general nature, directed to their overall strategy of enforcing their patent rights against generic competition. It is not specifically directed against plaintiffs, nor is there any evidence suggesting that it was made with plaintiffs in mind. The Federal

Circuit has held that a patent holder's statement that it intends to enforce its patent does not create a reasonable apprehension of suit. *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1054 (Fed. Cir. 1995)* (discussing *Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 889 (Fed. Cir. 1992)*). Accordingly, the court concludes that, under the totality of the circumstances, defendants did not engage in conduct sufficient to give plaintiffs a reasonable apprehension of suit at the time they filed the complaint at bar. The court, therefore, grants defendants' motions to dismiss for lack of subject matter jurisdiction. n17

n17 As noted above, the court is sympathetic to plaintiffs' situation. Plaintiffs must dwell within the frustrating Hatch-Waxman "bottleneck" (the expiration of Teva's 180-day period of exclusivity) before marketing their generic version of *quinapril* hydrochloride. The start of this exclusivity period presently, however, remains unknown and will not be triggered until either: (1) Teva voluntarily markets its generic *quinapril hydrochloride,* which it is not likely to do given the District of New Jersey's finding of infringement; (2) the District of New Jersey decides the issues of validity and enforceability of the '450 patent; or (3) another court declares the '450 patent invalid. Thus, subsequent ANDA filers, like plaintiffs, are placed in a conundrum when attempting to market their generic versions of brand drugs under the current regulatory framework.

[*42]

V. CONCLUSION

For the reasons stated, the court grants defendants' motions to dismiss for lack of subject matter jurisdiction. An order shall issue.

ORDER

At Wilmington this 28th day of June, 2004, consistent with the opinion issued this same date;

IT IS ORDERED that defendants' motions to dismiss (D.I. 8, 20) are granted.

Sue L. Robinson

United States District Judge